

**Remarks**

Applicants respectfully request that this application be reconsidered in view of the above amendments and the following remarks.

**1. Status of the Claims**

Claims 1-11, 15-17, 20-26, and 28-34 were pending in this application of which Claim 15-17 and 28-34 were withdrawn from consideration. In this response, Claims 1-11, 15-17, and 31-34 have been canceled. Accordingly, Claims 20-26, and 28-30 remain pending in this application, of which Claims 28-30 currently stand withdrawn.

**2. Rejection of Claims 1-11 and 20-26 under 35 U.S.C. §103(a)**

Claims 1-11 and 20-26 were again rejected under 35 U.S.C. §103(a) as being unpatentable over Moran et al. (US 6,576,793 B1). The cancelation of Claims 1-11 renders their rejection moot. Applicants respectfully traverse the rejection of Claims 20-26 for the reasons of record and for the following reasons.

**Rejection of Claims 20-26**

As required by M.P.E.P. §2143, to establish a *prima facie* case of obviousness, the Examiner must at least show (1) that the prior art reference teaches or suggests all the claim limitations, (2) that there is some suggestion or motivation, either in the reference or in the knowledge available to one of ordinary skill in the art, to modify the reference, and (3) that there is a reasonable expectation of success. Applicants continue to traverse this rejection because the Examiner has failed to meet the requirements for a *prima facie* showing of obviousness.

Claims 20-26 recite a pharmaceutical composition comprising *N*-{2-[4-((*R*)-2-hydroxy-2-phenylethylamino)phenyl]ethyl}-(*R*)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine dihydrochloride; a buffering agent; and water; wherein the buffering agent is present in an amount sufficient to provide the composition with a pH in the range of between about 4 and about 6.

The Office Actions in this application have failed to address the specific subject matter of Claims 20-26. Similarly, they have failed to consider Applicants' responses with respect to these claims.

Moran '793 does not teach or suggest a pharmaceutical composition with the limitations of Claim 20 and claims dependent therefrom. The reference, therefore, does not provide an enabling disclosure nor a reasonable expectation of success. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness for Claims 20-26 based on Moran '793.

Additionally, in assessing obviousness, objective evidence or secondary considerations such as unexpected results must be considered in every case in which they are present. (MPEP §2141 (III.) Applicants' specification discloses the particular advantages of the presently claimed pharmaceutical formulation for nebulizer administration. At page 9, lines 9-16, the specification provides objective evidence of the unexpected benefits of a pharmaceutical composition according to Claims 20-26, namely evidence of the stability of the pharmaceutical composition of Claims 20-26 upon storage. In contrast, U.S. 6,040,344 identified stability of a pharmaceutical composition of formoterol tartrate, a different  $\beta_2$  adrenergic receptor agonist, prepared for the same form of administration, as a limitation to its acceptability. Consideration of the present evidence of unexpected results, further supports the patentability of Claims 20-26.

In summary, Claims 20-26 have been shown to be patentable over Moran '793. Accordingly, the present rejection of Claims 20-26 under 35 U.S.C. §103(a) should be withdrawn.

### 3. Conclusion

In view of the foregoing, Applicants respectfully submit Claims 20-26 are in condition for allowance. Further, upon allowance, according to *In re Ochiai* (71F. 3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and MPEP §821.04, the restriction between Group I (Claims 20-26) and Group V (Claims 28-30), directed to the process of preparing the formulation of Claims 20-26, may be withdrawn.

Reconsideration of this application and prompt passage to allowance is respectfully requested. Should there be any issues regarding this application that may be resolved by telephone, the examiner is invited to telephone the undersigned agent for Applicants at (650) 808-3764 (direct).

Respectfully submitted,  
THERAVANCE, INC.

Date: October 24, 2007

By: Roberta P. Saxon  
Roberta P. Saxon, Ph.D.  
Registration No. 43,087

THERAVANCE, INC.  
901 Gateway Boulevard  
South San Francisco, CA 94080  
Tel: (650) 808-6000  
Fax: (650) 808-6078